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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,777	07/15/2003	William Howard Roark	PC25131A	8783

28880 7590 05/31/2006

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,777	ROARK, WILLIAM HOWARD	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *January 22, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This office action is in response to Applicant's amendment and election filed April 20, 2006 wherein claims 1, 5, and 6 are amended. Claims 1-10 are pending in this application and examined on the merits herein.

Applicant's election without traverse of group II drawn to compounds of structure (A) as pictured in instant claim 1 in which exactly one of X_1, X_2, and X_3 represents nitrogen, and there is no fused tricyclic ring system, is acknowledged. In view of Applicant's amendment to claim 6, groups II and VII are rejoined. Because Applicant made this election without traverse, the requirement for restriction is deemed proper and made final. Therefore, claims 1-10 in part have been examined insofar as they read on the elected invention. In particular, the following compounds disclosed in claims 3-4 have not been examined because they constitute non-elected subject matter:

4-{6-[3-(4-methoxy-phenyl-)-prop-1-ynyl]-1-methyl-2,4-diox- o-1,4-dihydro-2H-quinazolin-3-ylmethyl}-benzoic acid methyl ester;

4-[1-methyl-2,4-dioxo-6-(3-phenyl-prop-1-ynyl)-1,4-dihydro-2H-quinazolin- 3-ylmethyl]-benzoic acid;

4-{6-[3-(4-methoxy-phenyl-)-prop-1-ynyl]-1-methy- l-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-ylmethyl}-benzoic acid;

4-benzyl-7-(3-phenyl-prop-1-ynyl)-4H-[1,2,4]triazolo[4,3-a]quinazolin-5-one; 4-benzyl-7-[3-(4-methoxy-phenyl)-prop-1-ynyl]-4H-[1,2,4]triazolo[4,3-a]quinazolin-5-one;

4-{7-[3-(4-methoxy-phenyl)-prop-1-ynyl]-5-oxo-5H-[1,2,4]triazolo[4,3-a]quinazolin-4-ylmethyl}-benzoic acid methyl ester;

4-[5-oxo-7-(3-phenyl-prop-1-ynyl)-5H-[1,2,4]triazolo [4,3-a]quinazolin-4-ylmethyl]-benzoic acid;

and 4-(1-methyl-2,4-dioxo-6-(- 2-phenylethynyl)-1,4-dihydro-2H-quinazolin-3-ylmethyl)-benzoic acid;

Furthermore, it is noted that the aforementioned compounds lack antecedent basis in the parent claim 1 as currently amended, as they do not fall within the limitation, "of formula (A)." In particular, in formula (A) as amended, exactly one of X_1, X_2, and X_3 represents nitrogen, a limitation not met by any of the aforementioned compounds.

Groups I and III-VI are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 20, 2006.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Combination of an allosteric alkyne inhibitor of matrix metalloprotease 13 with valdecoxib.

Abstract

The following is a quotation from 37 CFR § 1.72:

> (b) A brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure." The sheet or sheets presenting the abstract may not include other parts of the application or other

> material. The abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length. The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure.

The abstract of the disclosure is objected to because it exceeds 150 words in length. In particular, the abstract as presented is 164 words in length. Furthermore, the abstract describes a combination of a MMP-13 inhibitor, "with celecoxib, or a pharmaceutically acceptable salt thereof," even though no claims in this application are drawn to any combinations comprising celecoxib. It is suggested that all references to celecoxib, and pharmaceutically acceptable salts of celecoxib, be removed, as celecoxib is not part of the claimed invention. This amendment would reduce the abstract to an allowable length. Correction is required. See MPEP § 608.01(b).

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cartilage damage and arthritis in a mammal, does not reasonably provide enablement for the treatment of all types of inflammation and pain using any possible combination of a compound of formula (A) with valdecoxib. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention concerns a method of using a pharmaceutical composition comprising valdecoxib and an allosteric inhibitor of matrix metalloprotease 13 of the structure (A) given in claim 1 for the treatment of a number of diseases, including arthritis, inflammation, cartilage degeneration, and pain.

The state of the prior art: Matrix metalloproteinase 13 is known to be a promising molecular target for anti-arthritis drugs. Its activity in the degradation of the extra-cellular matrix and destruction of cartilage is well known. Valdecoxib is known to be useful as a non-steroidal anti-inflammatory drug useful for the relief of symptoms of arthritis and other diseases characterized by inflammation. MMP-13 inhibitors are not known to be generally useful in the treatment of all kinds of pain or inflammation.

The treatment of pain is a complex art due to the fact that pain can be caused by many different disorders, and no one treatment is universally useful for the treatment of all pain. IN particular, pain is divided into neuropathic and nociceptive categories, representing pain arising from a disorder of the nervous system and pain arising from a

painful stimulus to the nerves, respectively. As described by Woolf et al. (Reference included with PTO-892) drugs used to treat nociceptive pain, including non-steroidal anti-inflammatory drugs such as valdecoxib, are often ineffective against neuropathic pain, such as that arising from nerve injury or diabetes, and vice versa. (p. 1959, left column, second paragraph) According to Woolf et al., "There is no treatment to prevent the development of neuropathic pain, nor to adequately, predictably, and specifically control established neuropathic pain." (p. 1959, left column, third paragraph) Valdecoxib, as described in US patent 5985902 (reference cited in PTO-892) is useful in a method for treating inflammation and inflammation-related disorders including pain. (Column 2, line 50 – Column 3, line 12, also Claims 14-21) No mention is made of valdecoxib or related compounds as being useful for the treatment of neuropathic pain or other kinds of pain not associated with inflammation.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While there exist many drugs for the treatment of pain and inflammation, there is no panacea which is capable of relieving all types of pain. Each individual drug for the treatment of pain must be evaluated on its own merits as to the specific cases in which is it or is not useful.

Additionally, combinations of drugs may produce interactions between drugs which may either inhibit the desired activities of the drugs being combined or else introduce undesirable side effects.

The Breadth of the claims: Claim 6 includes methods of treating all forms of arthritis, inflammation, cartilage damage, and pain using a combination of valdecoxib

and a compound of formula (A) which is a matrix metalloproteinase 13 inhibitor. No limitations are introduces as to the specific type of inflammation or pain to be treated.

Formula (A) includes a large number of compounds which share a bicyclic core structure with various substituents. The substituents may include various heterocyclic groups at least as complex as the core structure and capable of drastically altering the biological properties of the compound. These compounds are also additionally limited by the requirement that they possess allosteric inhibitory activity against matrix metalloproteinase 13. According to Silverman (Chapter 3, pp. 74-86, reference included with PTO-892) the binding of a drug to a receptor, and thus its biological activity, is affected by factors including the spatial arrangement of atoms within the molecule, chirality of the drug, and geometric isomerism. Groups $(Z)_n$-A-$(R_2)_q$ and W_2 of formula (A) are both inclusive of a broad range of functional groups which vary as to all three of these factors, and thus are expected to possess differing biological properties in addition to their ability to bind and inhibit MMP-13. Additionally, the various compounds of formula (A) may or may not produce deleterious interactions when combined with valdecoxib.

The amount of direction or guidance presented: It is shown in the instant specification that a number of compounds of formula (A) are allosteric inhibitors of matrix metalloproteinase 13. An assay is provided by which additional allosteric inhibitors of matrix metalloproteinase may be identified. Valdecoxib is already well known for the treatment of inflammation and pain, particularly that arising from arthritis. No protocols for the treatment of neuropathic pain are provided, nor is any method

provided by which compounds useful for the treatment of neuropathic pain could be readily identified. No evidence is given which would indicate that MMP-13 inhibitors and COX-2 inhibitors, when combined, possess any special synergistic effects against neuropathic pain. No guidance is given as to the possibility of interactions between compounds of formula (A) and valdecoxib.

The presence or absence of working examples: No working examples are provided for the treatment of any disorder in any subject. IN particular, no working examples are given for the treatment of neuropathic pain.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the pharmacology of matrix metalloprotease inhibitors and the treatment of neuropathic pain. See MPEP 2164.

The quantity of experimentation necessary: In order to treat neuropathic pain using the claimed pharmaceutical composition, a skilled practitioner of the art would undertake to develop a therapeutic regimen without precedent in the current state of the art. As the applicant's disclosure provides no guidance for the treatment of neuropathic pain, or any pain not associated with inflammation, the development of this therapeutic method would be an independent research endeavor which would present significant obstacles, mainly arising from the fact that neither of the drugs included in the claimed combination is known to affect any molecular target involved in neuropathic pain. This process would involve the screening of candidate compounds against relevant molecular targets, optimization of lead activity, and validation of lead compounds using

in vivo animal models of neuropathic pain. Developing such a therapeutic method without guidance from applicant's disclosure represents an undue experimental burden to one skilled in the art wishing to practice the invention.

Genetech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of precedent for treatment of neuropathic pain using MMP-13 inhibitors or COX-2 inhibitors, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of neuropathic pain.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-9 of copending Application No. ('174, cited in PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-10 are completely encompassed by the limitations of claims 1 and 4-9 of '174.

'174 claims, "A pharmaceutical combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof." (Claim 1) Instant claim 1 claims, "A combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric carboxylic inhibitor of MMP-13 of formula (A)." Thus instant claim 1, along with its dependent claims 2-4, is an obvious subspecie of claim 1 of '174.

Claim 4 of '174 claims, "A pharmaceutical composition, comprising a combination of valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier, diluent, or excipient." Instant claim 5 falls entirely within the limits of this claim and is thus an obvious subspecie of claim 4 of '174.

Claims 5-9 of '174. claim various methods of treating diseases comprising administering to an affected mammal, "a therapeutically effective amount of a combination of valdecoxib, or a pharmaceutically acceptable salt thereof, and an

allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof." The recited diseases are identical to those recited in instant claims 6-10, and the class of therapeutic compounds claimed by '174 entirely encompasses those recited by instant claims 6-10. The invention of instant claims 6-10 is thus an obvious subspecie of claims 5-9 of '174.

This is a provisional obviousness-type double patenting rejection as the conflicting claims have not in fact been patented.

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/620173 (Cited in PTO-892, herein referred to as '173) in view of Goldman et. al. (Included with PTO-1449).

Claim 1 of '173 claims a combination of a cox-2 inhibitor other than celecoxib or valdecoxib with an allosteric inhibitor of MMP-13 of formula (A). Formula (A), as recited in the claim, fully encompasses the definition of formula (A) given in instant claim 1 and incorporated within its dependant claims. The limitations introduced in dependant claims 2-10 of '173 parallel the limitations introduced in instant claims 2-10, introducing the same further limitations to the parent claim. Claims 1-10 of '173 do not claim combinations comprising valdecoxib or any pharmaceutical composition or therapeutic method involving such combinations. However, the specification of said copending application does not provide any reasoning by which valdecoxib alone among all COX-2 inhibitors is unsuitable for combination with an allosteric inhibitor of MMP-13.

Claim 5 of '173 claims a pharmaceutical composition comprising a selective COX-2 inhibitor that is not celecoxib or valdecoxib and an allosteric alkyne inhibitor of MMP-13. Claims 6-10 of '173 claim therapeutic methods for treating various diseases including cartilage damage, inflammation, arthritis, and pain involving said pharmaceutical composition. The MMP-13 inhibitors involved in these claims include inhibitors of formula (A) as described in the instant claims 1-10. The list of diseases to be treated is identical to that of instant claims 6-10. However, claims 5-10 of '173 to not include pharmaceutical compositions or therapeutic methods involving valdecoxib as the COX-2 inhibitor.

Goldman et. al. teaches that Valdecoxib is, "A COX-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea". (P. 1, title) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of '173 by using valdecoxib as the COX-2 inhibitor in the claimed combinations, compositions, and therapeutic methods instead of using a COX-2 inhibitor other than celecoxib or valdecoxib.

One of ordinary skill in the art would have been motivated to combine the teachings of the two references in order to treat diseases, such as osteoarthritis, that are caused by unbalanced MMP activity, while simultaneously treating the pain and inflammation caused by such conditions. One of ordinary skill in the art would have reasonably expected success because '173 already teaches a combination of a COX-2 inhibitor and an allosteric MMP-13 inhibitor, and because valdecoxib was already known to be a therapeutically effective COX-2 inhibitor for the treatment of arthritis and related

conditions. The claimed invention of claims 1-10 is an obvious subspecie of this variation of the invention of '173.

This is a provisional obviousness-type double patenting rejection as the conflicting claims have not in fact been patented.

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/619663 (Reference cited in PTO-892, herein referred to as '663) in view of Goldman et. al. (Included with PTO-1449).

Claims 1 and 4-9 of '663 claim combinations of a cox-2 inhibitor other than celecoxib or valdecoxib with an allosteric inhibitor of MMP-13, of undefined structure, as well as a pharmaceutical composition and method of treatment of disorders including cartilage damage, inflammation, arthritis, and pain involving said composition. The claimed MMP-13 inhibitors are not limited by structure and thus fully encompass the MMP-3 inhibitors included in instant claims 3-9. The combinations, pharmaceutical compositions, and therapeutic methods that are claimed are identical to those of instant claims 1-10 except that the MMP-13 inhibitors included may be of any structure and the COX-2 inhibitor must be a compound other than celecoxib or valdecoxib. Claims 1 and 4-9 of '663 do not claim combinations comprising valdecoxib or any pharmaceutical composition or therapeutic method involving such combinations. However, the specification of said copending application does not provide any reasoning by which valdecoxib alone among all COX-2 inhibitors is shown to be unsuitable for combination

with an allosteric inhibitor of MMP-13. In fact, paragraph 0006 of '663 specifically describes valdecoxib as being significantly safer than conventional NSAIDs for use in the treatment of arthritis.

Goldman et. al. teaches that Valdecoxib is, "A COX-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea". (P. 1, title) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teaching of '663 by using valdecoxib as the COX-2 inhibitor in the claimed combinations, compositions, and therapeutic methods instead of using a COX-2 inhibitor other than celecoxib or valdecoxib.

One of ordinary skill in the art would have been motivated to combine the teachings of the two references in order to treat diseases, such as osteoarthritis, that are caused by unbalanced MMP activity, while simultaneously treating the pain and inflammation caused by such conditions. One of ordinary skill in the art would have reasonably expected success because '663 already teaches a combination of a COX-2 inhibitor and an allosteric MMP-13 inhibitor, and because valdecoxib was already known to be a therapeutically effective COX-2 inhibitor for the treatment of arthritis and related conditions. The claimed invention of instant claims 1-10 is an obvious subspecie of this variation of the invention of claims 1 and 4-9 of '663, and is thus obvious over '663 in view of Goldman et al.

This is a provisional obviousness-type double patenting rejection as the conflicting claims have not in fact been patented.

Summary

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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